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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,649	09/04/2003	Yougandh Chitre	A03P1061	8324

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
01/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,649	CHITRE ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2007 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3, 4, 6-11 and 13-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 10 of copending Application No. 11/376,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a

preformed region adjacent the distal end of a cardiac lead to provide passive fixation is old and well known in the cardiac lead manufacturing arts. Preformed regions such as tines or pre-shaped lead body anchors have long been used to fix the lead to the heart. The examiner took Official Notice to this effect in the previous Office Action. Lacking any arguments to the contrary to effectively traverse the assertion, this feature is now considered admitted prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 4, 6-11 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. in view of Helland et al. (Pat. No. 5,545,201).

Regarding claim 1, Thompson et al. do not discuss the use of a helical tip electrode. Helland et al., however, disclose a cardiac lead wherein the active fixation helix is utilized as an electrode to provide bipolar pacing. Those of ordinary skill in the art would have readily recognized the use of a helical electrode to constitute a matter of obvious design. Such configurations are old and commonplace in the art when one desires to ensure good contact with the cardiac tissue. To utilize the fixation helix shown in Fig. 1B of Thompson et al. as an electrode in order to take advantage of the improved electrode/tissue interface contact would have therefore been considered blatantly obvious to anyone of ordinary skill. Related comments apply to claim 18.

Regarding claim 3 and claims with similar limitations, the examiner took Official Notice in the previous Office Action that it was old and well known in the cardiac lead arts to incorporate extendable/retractable helical tips in order to allow for precise

anchoring when implanting the lead. The extendable/retractable tip further lessens the chance for tissue damage upon progression of the lead in the vasculature. As the applicants have not effectively traversed this notice, the feature is now considered admitted prior art.

Regarding claim 9, although Thompson et al. are silent as to the exact spacing between a distal extremity of the lead and the defibrillation electrode, the applicants give no criticality to such spacing. Clearly the spacing depends upon the particular location of the lead within the heart and the various dimensions of the heart itself. Any distance along the lead allowing for effective electrode placement and efficient defibrillation would have been seen as an obvious matter of design to those of ordinary skill in the art looking to best treat the patient.

Limitations of claims not explicitly addressed above are considered clearly addressed by Thompson et al..

Response to Amendment

6. The declaration under 37 CFR 1.132 filed October 30, 2007 is insufficient to overcome the rejection of claims 1, 3, 4 and 6-23 based upon Thompson et al. in view of Helland et al. as set forth in the last Office action because: Declarations comparing applicant's invention/results thereof with those of the prior art must relate to the reference relied upon and the comparison must be with disclosure identical with that of the reference. Where the comparison is not identical with the reference disclosure, deviations should be explained or should be noted and evaluated. The evidence presented does not include data pertaining to the electrode surface areas involved in the test. Since the applicants disclose that the combination of electrode spacing and relative electrode surface area is an important factor in preventing T-wave oversensing (see par. 00042 of the present specification), any evidence presented to the examiner lacking information on such an important parameter will be considered insufficient. Without such knowledge, it is difficult to ascertain whether or not the test lead meets the scientific controls necessary to establish a showing of T-wave attenuation, or lack thereof in the lead of the prior art. Arguments of counsel cannot substitute for evidence.

Presuming for the sake of argument that the test lead electrodes have surface areas in the ranges disclosed suitable to attenuate T-waves in the context of the invention, it would appear that the test lead is of the same construction as the embodiment shown in applicants' Fig. 4 (i.e., sans a helical electrode and containing a tip cathode combined with a ring anode electrode). It is unclear how such an embodiment can "significantly" attenuate T-waves, yet a supposedly similarly constructed test lead and the lead of Thompson et al. allegedly cannot. This apparent contradiction was addressed in the previous Office Action as repeated below, but not addressed by the applicants.

The declaration under 37 CFR 1.132 filed April 30, 2007 is insufficient to overcome the rejection of claims 1, 3, 4 and 6-23 based upon Thompson et al. in view of Helland et al. as set forth in the last Office action and repeated above because: Declarations comparing applicant's invention/results thereof with those of the prior art must relate to the reference relied upon and the comparison must be with disclosure identical with that of the reference. Where the comparison is not identical with the reference disclosure, deviations should be explained or should be noted and evaluated. The evidence presented by the applicant compares two active fixation leads with tissue-penetrating distal helical electrodes and proximal ring electrodes spaced at varying distances. The evidence suggests that the spacing between electrodes is critical to the invention, but fails to establish that the helical tip itself provides any attenuation in T-wave amplitude. The examiner notes that the applicants' own Figure 4 shows a suitable lead embodiment without a helical tip. Paragraph 00042 of the present invention describes said embodiment as capable of preventing T-wave oversensing by virtue of the electrode surface areas and the spacing between electrodes. Paragraph 00043 of the present invention, in fact, admits that it would have been readily understood by those skilled in the art that leads may include passive or active fixation structures, and that both structures are old and well-known to those of ordinary skill in the art. Lacking sufficient evidence, it would only be reasonable for those of ordinary skill in the art to conclude that a prior art lead exhibiting electrodes with surface areas and spacings in

the ranges disclosed by the applicants would perform equally well. Declarations must set forth facts, not mere conclusions and the facts presented must be pertinent to the rejection. Otherwise, the declaration has no probative value. Applicant's attention is directed to MPEP 716 where the guidelines for a proper 1.132 affidavit or declaration are stated.

7. Regarding the issue of double patenting, the rejection must remain because all rejections have not been overcome.

Conclusion

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
January 6, 2008

KENNEDY SCHAETZLE
PRIMARY EXAMINER